

US Environmental Protection Agency Office of Pesticide Programs

Office of Pesticide Programs Microbiology Laboratory Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for Guidelines for Use and Maintenance of Laboratory Notebooks and Project Binders

SOP Number: ADM-05-01

Date Revised: 09-13-07

Superseded SOP: ADM-05-00 - Guidelines for Use and Maintenance of

Laboratory Notebooks and **Project Binders**

EPA/OPP MICROBIOLOGY LABORATORY ESC, Ft. Meade, MD

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1.0 SCOPE AND APPLICATION:

1.1 The purpose of this SOP is to provide guidance on the use and maintenance of laboratory notebooks and project binders for laboratory activities. For the purpose of this SOP, "laboratory notebook" is defined as a bound collection of serially numbered pages used to record the planning and progress of scientific investigation. A "project binder" is defined as a loose-leaf collection of dated and serially numbered hand-written and/or computer-generated documents and forms, graphs, tables, notes, and data.

2.0 DEFINITIONS:

- 2.1 ATP = Antimicrobial Testing Program
- 2.2 GLP = Good Laboratory Practice Standards
- 2.3 QAU = Quality Assurance Unit
- 3.0 <u>HEALTH AND SAFETY</u>: Not applicable.
- 4.0 CAUTIONS: None
- 5.0 <u>INTERFERENCES</u>:
 - 5.1 Lack of cross-referencing between a notebook and binder or between two analysts' notebooks or binders could make interpretation of information difficult.

6.0 PERSONNEL QUALIFICATIONS:

- 6.1 Personnel are required to be knowledgeable of the procedures in this SOP.

 Documentation of training and familiarization with this SOP can be found in the training file for each employee.
- 7.0 SPECIAL APPARATUS AND MATERIALS: None
- 8.0 <u>INSTRUMENT OR METHOD CALIBRATION</u>: Not applicable
- 9.0 <u>SAMPLE HANDLING AND STORAGE</u>: Not applicable
- 10.0 PROCEDURE AND ANALYSIS:
 - 10.1 The laboratory notebook and/or project binder may be the primary record of

planning, purpose, and experimental work. It represents a daily record and is a permissible way to document laboratory experimental work indicating daily purpose and conclusions as well as data and observations.

- 10.1.1 The main purposes of maintaining a laboratory notebook and/or project binder are to preserve experimental planning, protocol development, conduct of the study, data and observations, conclusions and recommendations of future direction in a form that can be understood by another scientist. This is done so the purpose and planning of the study is understood and studies or research projects may be reconstructed, repeated, and defended.
- 10.1.2 Quality control activities and practices related to equipment maintenance and calibration are recorded on the appropriate forms and maintained in log books. It is not necessary to record these activities in the laboratory notebook though these forms should be referred to and cross-referenced in the laboratory notebook or binder data sheets.
- 10.1.3 A laboratory notebook or project binder may contain more than one research project when documenting experimental options, initial planning, or preliminary observations. Using both with cross-referencing is recommended.
- 10.1.4 Laboratory notebooks, project binders, their contents, and any associated materials are property of the OPP Microbiology Laboratory. They should be kept in a secure location while the project is ongoing. As projects are completed, the materials are retired. A log of all active and retired notebooks and binders is maintained on G:\DATA\SHARED\APPB\ANTIMICROBIAL TESTING PROGRAM\LAB Notebooks (see Attachment 1). It is the responsibility of each analyst to populate this notebook log. The notebook log will be reviewed by the Branch Chief or designee on a regular basis to ensure that it accurately reflects the status of notebooks and binders.
- 10.2 Laboratory Notebook and Project Binder Format:
 - 10.2.1 <u>Title Page</u>: On the title page, record name, phone number, the laboratory office (OPP Microbiology Laboratory, Environmental Science Center, Ft. Meade, MD), the date the notebook was started and ended, the number of the notebook in the sequential series as needed, and the project title, study protocol or research protocol, for

- which the notebook is used (see Attachment 2). Depending on the anticipated size of the project, an analyst may use a notebook for one or several projects.
- 10.2.2 <u>Table of Contents</u>: Reserve several pages following the title page for recording a running table of contents. Record the Study Protocol or Research Protocol title and project identification number followed by the pages used during that investigation.
- 10.2.3 <u>Experimental descriptions</u>: Separate experiments using clearly stated descriptions and/or dates. List the experiments in the Table of Contents.
- 10.2.4 <u>Page numbering</u>: Every page of the laboratory notebook should be sequentially numbered, including the title page and the pages reserved for table of contents. Pages should not be skipped or discarded.
- 10.3 The following are general guidelines documenting work associated with planning, protocol development, performing lab work, recording project data, information, and observations.
 - 10.3.1 Document the daily plan of the experiment before initiating lab work. Date and initial each daily entry. Include a short description of the purpose of the investigation. In many cases, the plan is in the form of a research protocol which should be affixed in the notebook. Changes in plan should be documented.
 - 10.3.2 Plan how to document the experiment in the notebook or binder prior to making any entries. Much of this can be done by using data sheets from SOPs. Consider that room may be needed for tables, observations, graphs, spreadsheets, and statistical analysis. Writing should be legible, grammatically correct, and factually complete. Avoid using the notebook for scratch work or personal information. Think carefully before writing.
 - 10.3.3 The laboratory notebook and/or project binder should be available in the lab while conducting a study or research. Don't rely on memory.
 - 10.3.4 Control the location of and access to the laboratory notebook and/or project binder. Secure them in a closed or locked cabinet or file drawer when not in use.

- 10.3.5 All entries should be made in permanent ink and should be as complete as possible. If others are assisting with an experiment or with recording information, they should initial and date entries. Documentation should indicate who did what step or portion of the experiment.
- 10.3.6 Make notes and observations clear, concise, yet detailed, and complete. Unusual or unique observations, background information that would lead to further experimentation should be entered into the notebook.
- 10.3.7 Provide full detail of all experimental procedures and conditions. Any SOPs or portions of SOPs that are being used should be referenced and any deviations should be documented. If in doubt, include the observation or procedure.
- 10.3.8 Any graphs, drawings, or printouts should be carefully affixed in the notebook using as permanent a method as possible (glue, staples).

 Reference should be made to any affixed material on the bound page and analysts should sign and date over the interface.
- 10.3.9 If graphing programs, spreadsheets, or statistical software are used, the name of the program and the version number should be documented.
- 10.3.10 Each section should have a clear descriptive heading.
- 10.3.11 The contents of the laboratory notebook and/or project binder should be frequently peer-reviewed during the course of a study. The peer reviewer should sign and date each portion that is reviewed.
- 10.3.12 Clearly define all abbreviations, code names, or product codes.

 Commonly used abbreviations need only be defined the first time used
- Draw a line through all errors followed by a date, initials, and a brief explanation for the correction (codes may be used for common error types such as EE for entry error and EEO for entry error omission). Do not erase or use white out. The original entry should be visible.
- 10.3.14 If large sections need to be corrected, the section should be blocked and struck out with one diagonal line from corner to corner followed by a date, signature, and short explanation for the strike out. The original uncorrected section should still be visible.

- 10.3.15 If an experiment takes more than one page, indicate the continuation at the bottom of the first and any subsequent pages, along with your initials and date.
- 10.3.16 If a long term experiment is interrupted by other daily entries, indicate that the experiment is continued on the appropriate page number, along with your initials and date.
- 10.3.17 If a page is inadvertently skipped during the course of an investigation, cross out the whole page, and sign and date the line.
- 10.3.18 Avoid writing too near the binding as this area may not photocopy well.
- 10.3.19 All laboratory notebooks and project binders for a particular project should be numbered sequentially. Cross-reference multiple notebooks when necessary.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Active notebooks and binders should be kept by the analyst in a secure location. After completion of a project, retired notebooks and project binders are archived in secure file cabinets in the file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 **QUALITY CONTROL**:

- 13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practice Standards. Appropriate quality control measures are integrated into each SOP.
- For quality control purposes, the required information is documented in the laboratory notebook or on the appropriate record form(s) (see 6.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any instances of non-compliance with this SOP will be corrected upon discovery.

15.0 <u>REFERENCES</u>:

- 15.1 Writing the Laboratory Notebook, H.M. Kanare, American Chemical Society, 1985.
- 15.2 US EPA Good Laboratory Practice Standards, Title 40 Code of Federal Regulations (CFR) Part 160.

16.0 FORMS AND DATA SHEETS:

- 16.1 Attachment 1
 Example of Notebook Log
- 16.2 Attachment 2 Example of Title Page

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Attachment 1: Example of Notebook Log Notebook Log OPP Microbiology Laboratory

| Notebook or Binder ID* | Project(s) Description(s) | Research or Study Protocol or Project Code | Date Started | Date Retired | Notebook Location (Office # or Archive Room) |
|---------------------------|---------------------------|--|--------------|--------------|--|
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^{*} Notebook ID = initials of analysts and a chronological # (e.g. XY-1, XY-2, XY-3, etc.)

Attachment 2: Example of Title Page

| | OPP Microb Print Clearly- U | iology Lab Use black ball po | oint pen | | | |
|--|--------------------------------|---------------------------------|----------|--------|--|--|
| Notebook No. | · | | | | | |
| | (Analysts name) | | | | | |
| | (signature) | | | | | |
| | (ID-code) | | | | | |
| | (department(s)) | | | | | |
| | (day) | (month) | (year) | | | |
| to be kept in | (location) | | | | | |
| Research or Study Protocol or Project Code | (Title(s) and tracking | number(s)) | | | | |
| | | | | | | |
| No further en | | | | | | |
| | | (day) | (month) | (year) | | |
| Received for | storage on | (day) | (month) | (year) | | |
| Related work | continued in r | notebook no. | | | | |